

PATENT APPLICATION

**EXPANSILE DEVICE FOR USE IN BLOOD VESSELS AND TRACTS IN
THE BODY AND METHOD**

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EXPANSILE DEVICE FOR USE IN BLOOD VESSELS AND TRACTS IN THE BODY AND METHOD

CROSS-REFERENCES TO RELATED APPLICATIONS

- 5 **[0001]** This application is a continuation-in-part of and claims benefit of priority from U.S. Patent Application No. 10/272,508, filed October 15, 2002, which is a continuation of U.S. Patent Application No. 09/528,574, filed March 20, 2000 and issued as U.S. Patent No. 6,464,712 on October 15, 2002, which is a continuation-in-part of U.S. Patent Application No. 09/241,680, filed February 1, 1999 and issued as U.S. Patent No. 6,056,770 on May 2, 2000, which is a continuation-in-part of U.S. Patent Application No. 08/972,383, filed November 18, 1997 and issued as U.S. Patent No. 5,922,009 on July 13, 1999, which is a continuation-in-part of U.S. Patent Application No. 08/798,870, filed February 11, 1997 and issued as U.S. Letters Patent No. 5,782,860 on July 21, 1998. The above-identified U.S. Patent Applications are each incorporated herein by reference.

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BACKGROUND OF THE INVENTION

- 20 **[0002]** This invention relates to an expansile device for use in vascular access tracts and non-vascular tracts in the human body and method and more particularly for percutaneous occlusion of vascular access sites in the human body.
- 25 **[0003]** Percutaneous access to the blood vessels and organs of the human body for diagnosis and treatment of disease processes has heretofore been accomplished.
- 30 **[0004]** Percutaneous vascular procedures are performed involving the coronary, peripheral and cerebral vasculature. These procedures include coronary and peripheral angiography, angioplasty, atherectomies, coronary retroperfusion and retroinfusion, cerebral angiograms, treatment of strokes, cerebral aneurysms and the like. Patients undergoing such procedures are often treated with anti-platelet drugs, anticoagulants such as heparin, thrombolytics, or a combination thereof, all of which interfere with coagulation making it more difficult for the body to seal a puncture site. Various devices and methods have heretofore been utilized, however, they all have had deficiencies, including the use of complicated devices and methods. In addition, difficulties are still encountered in obtaining good seals. There is therefore a need for a device and method for percutaneous access and occlusion of vascular

access sites and other puncture sites and natural tracts in the human body which overcome the deficiencies of prior art devices and methods.

BRIEF SUMMARY OF THE INVENTION

- 5 **[0005]** In general, it is an object of the present invention to provide an expansile or closure device and method for percutaneous access and occlusion of vascular access sites, other puncture sites and natural tracts involving various organs having lumens or cavities in the human body which will make possible a positive seal of the puncture site or tract promoting rapid healing of the puncture site or tract.
- 10 **[0006]** Another object of the invention is to provide a closure device and method of the above character which can be easily and reliably used.
- [0007]** Another object of the invention is to provide a closure device and method of the above character which permits easy placement of the device without measuring or sizing of the tract or device.
- 15 **[0008]** Another object of the invention is to provide a closure device and method of the above character which can be deployed or made operative with one maneuver or movement.
- [0009]** Another object of the invention is to provide a closure device and method of the above character which can be deployed and is effective in severely tortuous vessels.
- 20 **[0010]** Another object of the invention is to provide a closure device and method of the above character which enables continued substantially unobstructed blood flow during deployment and use of the closure device.
- [0011]** Another object of the invention is to provide a closure device and method of the above character in which no foreign body remains in the blood vessel.
- 25 **[0012]** Another object of the invention is to provide a closure device and method of the above character that permits early ambulation of patients and avoids prolonged bed rest.
- [0013]** Another object of the invention is to provide a closure device and method of the above character which reduces the risk of bleeding, formation of arteriovenous fistula, formation of pseudoaneurysm, thrombosis with distal embolization and infection.
- 30 **[0014]** Another object of the invention is to provide a closure device and method of the above character that reduces the risk of causing ischemia of an extremity.

- [0015] Another object of the invention is to provide a closure device and method of the above character that is inexpensive, quick, safe, easy to use and is disposable.
- [0016] Additional objects and features of the invention will appear from the following description in which the preferred embodiments and the methods using the same are
- 5 described in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

- [0017] The following drawings should be read with reference to the detailed description. Like numbers in different drawings refer to like elements. The drawings, which are not necessarily to scale, illustratively depict embodiments of the present invention and are not intended to limit the scope of the invention.
- [0018] Figure 1 is a side-elevational view partially in section of an expansile or closure device for obtaining percutaneous access and occlusion of tracts and punctures in the human body incorporating the present invention without the tip guide and having the expansile member in a deployed or expanded position.
- [0019] Figure 2 is a side-elevational view partially in section of the device in Figure 1 with the expansile assembly in a de-deployed or contracted configuration.
- [0020] Figure 3 is an exploded side-elevational view in section showing the handle assembly and stop mechanism of the device of Figures 1-2.
- 20 [0021] Figure 4 is a cross-sectional view taken along the line 4-4 of Figure 3.
- [0022] Figure 5 is a cross-sectional view extending distally for several millimeters taken along the line 5-5 of Figure 3.
- [0023] Figure 6 is a side-elevational view partially in section of another embodiment of the device of the present invention without the tip guide and having the expansile member in the expanded configuration.
- 25 [0024] Figure 7 is a side-elevational view partially in section of the device in Figure 6 with the expansile assembly in a de-deployed or contracted configuration.
- [0025] Figures 8a and 8b are exploded cross-sectional views of the distal extremity of another embodiment of the device of the present invention showing the expansile assembly in
- 30 the expanded configuration occluding a puncture in a blood vessel. Figure 8a shows the

expansile assembly of the device without proximal tension applied thereto and Figure 8b shows the expansile assembly of the device with proximal tension applied thereto.

[0026] Figure 9A-9D are cross-sectional views of a distal end of the expandable device illustrating yet another embodiment according to the principles of the present invention.

5 [0027] Figure 10A-10E are cross-sectional views of a distal end of the expandable device illustrating still another embodiment according to the principles of the present invention.

[0028] Figure 11A-11E are cross-sectional views of a distal end of the expandable device illustrating a further embodiment according to the principles of the present invention.

10 DETAILED DESCRIPTION OF THE INVENTION

[0029] In general, the device for expansion within an organ having a wall defining a lumen or cavity in the body of the present invention comprises an elongated tubular member having proximal and distal extremities and having a longitudinal axis. An expansile member is carried by the distal extremity of the elongated tubular member and is movable between

15 contracted and expanded configurations. A deformable membrane at least partially covering the expansile member is sized so as to be capable of expanding as the expansile member moves from the contracted configuration to the expanded configuration. Deployment means are carried by the proximal extremity of the elongated tubular member and coupled to the expansile member. The deployment means are adapted to be capable of moving the
20 expansile member between the contracted and expanded configurations. A handle assembly is carried by the proximal extremity of the elongated tubular member and coupled to the deployment means.

[0030] More specifically, as shown in Figures 1-2, the expansile device 21 of the present invention comprises a first elongate tubular member 22, preferably a flexible elongate tubular member 22, formed of a suitable plastic material, preferably a cast thermoset material such as polyimide. The inner and outer surfaces of the polyimide material may be coated with a lubricious material such as Teflon™. Alternatively, the thermoset material may be a polyimide-Teflon™ composite in order to provide the desired lubricious inner and outer surfaces. The first flexible elongate tubular member 22 has proximal and distal extremities
25 23 and 24 with a longitudinal axis extending from the proximal 23 to the distal extremity 24

and is provided with a first lumen 26 circular in cross section which, as shown, may be centrally disposed extending from the proximal extremity 23 to the distal extremity 24.

[0031] The flexible elongate tubular member 22 is of a suitable size, as for example having an outer diameter ranging from 1-9 French corresponding to an outer diameter ranging from approximately .008" to .050", preferably approximately .022"-.026", and a suitable length, as for example 10-150 centimeters, preferably 33 centimeters \pm 1 centimeter. The first lumen 26 in the first flexible elongate tubular member 22 may have an inside diameter of approximately .003" to .030", preferably .012"-.014".

[0032] Expansile means in the form of an expansile assembly 31 is carried by the distal extremity 24 of the flexible elongate tubular member 22 and is movable between contracted and expanded positions. A deployment mechanism is carried by the proximal extremity 23 of the flexible elongate tubular member 22 and adapted to be operated by the human hand for movement from a contracted position or configuration to an expanded position or configuration.

[0033] The expansile assembly 31 includes an expansile member 32 and a membrane 33 which at least partially covers the expansile member 32. As shown in Figure 2, the expansile member 32 is in a form having a complex geometrical configuration, preferably a ellipsoidal, helical or bi-conical coil configuration 34, when in the free, unconstrained state. As hereinafter discussed, the helical coil 34 is formed of a suitable material such as a shape memory or superelastic material which can be elongated, contracted or constrained without permanent deformation but, at body temperature, when freed or unconstrained returns to the memorized helical coil configuration 34 to which it has been annealed. One material found to be particularly suitable for such an application is a nickel/titanium alloy wire, often called Nitinol™ wire.

[0034] The correctly annealed and configured helical coil 34 has a plurality of generally circular turns, loops or coils creating, preferably, a proximal coil, loop or turn 66, a middle coil, turn or loop 67 and a distal coil, turn or loop 68 as shown in Figure 1. The proximal, middle and distal coils 66, 67 and 68 are generally nonplanar with respect to one another. At least a portion of the proximal coil 66 and a portion of the distal coil 68 each lie in a plane that is generally parallel to one another and generally perpendicular to the longitudinal axis of the flexible elongate tubular member 22. The middle coil 67 is non-planar and helical as it

connects the proximal and distal coils 66 and 68 so that the unconstrained or free helical coil 34 assumes a substantially ellipsoidal or bi-conical shape.

[0035] The middle coil 67, when freed or unconstrained, has a suitable diameter ranging from 3 to 10 millimeters, preferably, greater than or equal to 5.33 millimeters (16 French).

- 5 As hereinafter discussed, during deployment the middle coil 67 is partially flattened and constrained by the membrane 33 to maintain a diameter of approximately 16 French in order to overlap a puncture site or other opening to assist in occluding the opening. The proximal and distal coils 66 and 68 are of approximately equal size and diameter ranging from 1 to 5 millimeters, preferably 2 to 3 millimeters. The unconstrained helical coil 34 configuration
- 10 has a distance from the proximal 66 to the distal 68 coil of approximately 4-8 millimeters. As hereinafter discussed, the helical coil 34 is retracted into the flexible elongate tubular member 22 to obtain the de-deployed configuration wherein the contracted, constrained diameter corresponds to the approximate diameter of the Nitinol wire used to construct the expansile member 32, ranging from .002" to .010", preferably .0055". As hereinafter discussed, the
- 15 expansile member 32 is provided with a straight portion 73 of Nitinol wire proximal to the helical coil 34 having a length of approximately 50 millimeters ± 2 millimeters.

[0036] The deployment means or mechanism 80 includes a push-pull element or member 81, preferably in the form of a wire 81 with proximal and distal extremities 82 and 83, which is slidably disposed in and extends through the first lumen 26 of the flexible elongate tubular

- 20 member 22 as hereinafter discussed. The push pull member 81 is formed of a suitable material such as stainless steel in order optimize torque transmission. The push pull member 81 has a suitable diameter ranging from approximately .005"-.020", preferably .010". In order to provide for optimal torque transmission after being bonded to the Nitinol expansile member 32 as hereinafter discussed, the distal extremity 83 of the push pull wire 81 provided
- 25 with a tapered portion. The tapered portion has a length ranging from approximately 1.0 centimeters to 6.0 centimeters.

[0037] A hypotube connector is provided for joining the tapered portion of the push pull wire 81 to the proximal straight portion 73 of the Nitinol wire 61. The hypotube connector has a length ranging from approximately 2.0 centimeters to 4.5 centimeters, an inner diameter

30 ranging from approximately .006"-.008" and an outer diameter ranging from approximately .009"-.012". During manufacture, the tapered portion of the push-pull wire 81 is inserted into one end of the hypotube connector and the proximal end of the straight portion 73 of the

Nitinol wire is inserted into the opposite, distal end of the connector whereupon all are bonded together within the hypotube connector utilizing a suitable adhesive such as Loctite™ 648. It should be appreciated that, by grinding and shaping a single length of Nitinol wire, one piece can be utilized having a distal thinner segment which can be shaped into the coil.

- 5 This obviates the requirement of having a stainless steel push-pull wire, hypotube and connection therebetween.

[0038] The proximal end 23 of the flexible elongate tubular member 22 is provided with an expander tube or strain relief member 113 made of a suitable material, such as polycarbonate, having an inner diameter ranging from 5.024"-.028", an outer diameter ranging from .030"-.036" and a length of approximately 24-26 millimeters. The expander tube 113 is disposed over the proximal end 23 of the tubular member 22 so that the proximal end of the expander tube 113 is positioned approximately 0.5-1.0 millimeters distal to the proximal most end 23 of the tubular member 22 and suitably bonded thereto using an appropriate adhesive such as cyanoacrylite.

- 15 [0039] As shown in Figures 1-3 , a stop mechanism or means 121 is provided to control the range of movement or travel of the push-pull wire 81 during deployment and de-deployment of the expansile assembly 31. The stop mechanism 121 comprises first and second, or inner and outer, slidably and rotatably nested, or coaxially carried stop members or handles 122 and 123 which are formed of polycarbonate and mounted as hereinafter discussed.

- 20 [0040] The inner stop member or handle 122 is formed of a polycarbonate extrusion which, initially, has an outer configuration that is square in cross section and has a dimension ranging from approximately .015"-.050", preferably approximately .038". The inner member 122 has a length of approximately 60 millimeters \pm 5 millimeters and carries a circular in cross section lumen extending therethrough, the lumen having a diameter ranging from approximately .010"-.016". During manufacture, the inner stop member 122 is twisted or turned in order to form a threaded outer surface or helical groove 125 therein which carries pitches of varying degrees or distances. As shown in Figure 3, the thread 125 carries, preferably, a greater pitch on the proximal segment of the inner handle 122 and a lesser pitch on the distal segment of the inner handle 122.

- 25 [0041] The distal end of the inner handle 122 carries a collar 124 formed of cyanoacrylite and having a length of approximately 3-5 millimeters and an outer diameter ranging from approximately .024"-.040". The outer collar 124 is coaxially adhesively mounted over the

inner handle 122 so that the distal end of the collar 124 is disposed slightly proximal to the distal end of the inner handle tube 122 by several millimeters.

[0042] As seen in Figure 3, an inner handle support hypotube 127 is coaxially, adhesively mounted upon the proximal extremity 82 of the push-pull wire 81 using, preferably,

5 cyanoacrylite so that the proximal end thereof is flush with the proximal most tip of the push pull wire 81. The support hypotube 127 has an inner diameter ranging from .008" to .018", preferably approximately .012" and an outer diameter ranging from .015" to .028", preferably approximately .020". The inner handle 122 is coaxially, adhesively mounted upon the support hypotube 127, also using an appropriate adhesive such as cyanoacrylate, so that the proximal end 82 of the push-pull wire 81 and the support hypotube 127 carried thereby extend through and proximal of the inner handle 122 as hereinafter discussed.

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[0043] The outer handle stop member 123 is constructed from metal, polymer, plastic, or like materials, and preferably comprises stainless steel. The stop member 123 has a length of approximately 65 millimeters \pm 5 millimeters, an inner diameter ranging from approximately 15 .020"-.060", preferably approximately .055", and an outer diameter ranging from approximately .035"-.080", preferably approximately .066". In addition, the proximal end of the outer stop member 123 is provided with a slotted stop segment or inner nut or bushing 126 which has an outer diameter equal to the outer diameter of the outer stop member 123 and which is formed so that the slot 126 is square in shape and has a dimension which is, 20 preferably, approximately .042" or slightly larger than the square, outer dimension of the inner handle 122. As shown in Figures 1-3, the distal end of the outer handle 123 is secured to the proximal extremity 23 of the elongate tubular member 22 by being adhesively secured to the proximal end of the expander tube 113 using, preferably, an ultra violet cured adhesive. As shown in Figures 1-3, a freely rotatable handle assembly 131 is provided and carried by 25 the segments of the push-pull wire 81 and inner handle support hypotube 127 extending proximal to the inner handle 122. The rotatable handle assembly 131 comprises a rotatable hypotube casing 132, a rotatable collar 133, a back stop member 134 and a handle grip or sleeve 136 as hereinafter discussed. The complete assembly 131 is sized so as to be capable of being passed through a conventional introducer sheath as hereinafter described. As such, it 30 has a maximum diameter that is no greater than, and, preferably less than, approximately two to three times the diameter of the elongate tubular member 22.

[0044] The hypotube casing 132 is of appropriate size, having a length of approximately 15 millimeters, an inner diameter of approximately .035" and an outer diameter of approximately .042". The hypotube casing 132 is covered with a handle grip or sleeve 136 made of an approximately 15 millimeters length of RNF heat shrink tubing having a thickness of 5 approximately 1/16" and which is applied in a conventional manner.

[0045] The rotatable collar 133 is constructed of hypotube having a length of approximately 8 millimeters, an inner diameter of approximately .025" and an outer diameter of approximately .032". The collar 133 is adhesively, coaxially mounted within the casing 132 using an appropriate adhesive, preferably cyanoacrylite, so that the distal end of the 10 collar 133 is flush with the distal end of the casing 132. The rotatable collar 133 carried by the casing 132 is coaxially rotatably mounted over the proximal end of the inner handle support hypotube 127 as shown in Figures 1-3.

[0046] A back stop member 134 constructed of stainless steel hypotube and having a length of approximately 4 millimeters, an inner diameter of approximately .025" and an outer 15 diameter of approximately .032" is adhesively, coaxially mounted (also preferably using cyanoacrylite) on the proximal end of the inner handle support tube 127 proximal to the rotatable collar 133 so that the proximal end of the stop member 134 is flush with the tip of the proximal end of the inner handle support tube 127.

[0047] As assembled, the push-pull element 81, with the threaded inner handle member 20 122 affixed thereto and the collar 124 carried thereby, is movable longitudinally and rotationally within and in relation to the outer handle member 123 which has its distal extremity secured to the expander hypotube 113 carried by the proximal extremity 23 of the polyimide tubular member 22 as hereinbefore discussed. Using the freely rotatable handle assembly 131, it is movable between a forward or distal most position wherein the distal end 25 of the inner handle 122 is engaged with or abutting against the proximal extremity 23 of the polyimide member 22 and the distal end of the rotatable collar 133 abuts against the proximal end of the stop segment 126 of the outer handle member 123 and a rearward or proximal most position wherein the collar 124 is engaged with the stop segment 126 carried by the proximal extremity of the outer member or handle 123 and the proximal end of the rotatable 30 collar 133 abuts against the distal end of the back stop member 134. As hereinafter discussed, these positions correspond to deployed and de-deployed positions and configurations of the expansile assembly 31.

[0048] The distal extremity 24 of the flexible elongate tubular member 22 is provided with a hypotube tip 105 over which the membrane 33 is disposed and moves as hereinafter discussed. The hypotube tip 105 is constructed of 304 stainless steel hypotube, or other suitable material, having an outer diameter ranging from approximately .028"-.040" and an inner diameter ranging from .024"-.030" and which is cut to have a length of approximately 3-5 millimeters. The hypotube tip 105 is coaxially mounted over the distal extremity 24 of the polyimide tubular member 22 using, preferably, Loctite so that the tip of the distal extremity 24 of the tubular member 22 is flush with the distal end of the hypotube tip 105.

[0049] A tip guide (not shown) is slidably carried by the polyimide tubular member 22 for use as hereinafter discussed. The tip guide is constructed of 1/16" RNF 100 Shrink tubing. The tip guide has a longitudinal axis and a length of approximately 32 millimeters. In addition, the distal portion of the tip guide is provided with a larger, non shrunk end.

[0050] As hereinbefore discussed, the expansile assembly 31 also carries a deformable flexible membrane 33 which is carried by and secured to the distal extremity 24 of the elongate tubular member 22 as shown in Figures 1-2.

[0051] The membrane 33 is formed of Polyblend™ Extrusion having an internal or inner diameter of .020", an outer diameter of .036" and which is cut to have a length of approximately 1 centimeter ± 1. The proximal end of the membrane 151 is secured to the proximal end of the hypotube tip 105, using an appropriate material such as Loctite 496 adhesive, so that the distal membrane tip 152 extends distal to the tip of the distal extremity 24 of the flexible elongate tubular member 22 and so that distally extending portion of the membrane tip 152 has a length, measured from the distal end of the hypotube tip 105 to the distal end of the membrane tip 152, of approximately 1.0-1.5 millimeters. The extruded membrane tip 152 is subsequently sealed or closed with an extrusion beading 153 as hereinafter discussed.

[0052] The beading 153 is made of the same or similar Polyblend material in the form of a solid plug having a diameter of 0.025" and a length of 5 millimeters. This segment of extrusion beading 153 is inserted into the distal, open end of the membrane tip 152 approximately 0.5-0.75 millimeters and heat bonded to the membrane tip 152 so that the distal tip of the beading 153 is flush with the distal end of the membrane tip 152.

[0053] Operation and use of the expansile device 21 of the present invention is similar to that disclosed in U.S. Patent No. 5,782,860, issued July 21, 1998 and U.S. Patent No.

5,922,009, issued on July 13, 1999, the relevant portions of which are hereby incorporated by reference in their entirety.

- [0054] Prior to deployment, the expansile member 32 is fully or completely retracted within the distal extremity 24 of the flexible elongate tubular member 22 which causes the 5 expansile member 32 to assume a contracted configuration. Insertion of the device 21 in the contracted configuration into a conventional sheath introducer (not shown) is facilitated by using the tip guide 106 carried by the polyimide tubular member 22 as hereinbefore discussed. Prior to inserting the device 21 into the sheath introducer, the operator slides the tip guide 106 distally, from the middle of the polyimide tubular member 22 to the distal 10 extremity 24 thereof. When the distal end of the tip guide 106 is disposed slightly distal to the distal extremity 24 of the polyimide tubular member 22 and the membrane 33 carried thereby, the distal end of the tip guide 106 is frictionally fit into the conventional one-way valve carried by the sheath introducer, thus urging the valve into a slightly opened position. The distal extremity 24 of the elongate tubular member 22 can then be easily and 15atraumatically introduced through the valve of the introducer and advanced distally therein until the device is aptly disposed through the tract opening or, in the case of a vascular puncture, in the blood vessel as hereinbefore discussed. By not relying on the tip of the distal extremity 24 of the device 21 to open the valve of the introducer sheath, the integrity of the membrane 33 carried thereby is maintained.
- 20 [0055] Once appropriately disposed in a tract or puncture site, deployment of the device 21 is accomplished by using the freely rotatable handle assembly 131 to operate the deployment means 80 to move the push-pull wire 81 distally to urge the expansile member 32 distally out of the lumen 26 of the flexible elongate tubular member 22, into the membrane 33. As soon as the distal part of the expansile member 32 clears the lumen 26, it begins an attempt to 25 expand into its shape memory, predetermined, or free configuration which corresponds to the ellipsoidal, helical coil configuration 34. However, as hereinafter discussed, the expansile member 32 is prevented from fully expanding into its free shape configuration as a result of the membrane 33 partially constraining the expansion process.

- [0056] More specifically, the distal coil 68 operates to expand the membrane 33 initially to 30 a small degree. This initial process avoids sudden gross distortion of the membrane 33. As soon as the expansile member 32 moves further distally out of the lumen 26 and expands into the membrane 33, the non-adherent portion of the membrane 33, distal to the portion of

membrane 33 fixed to the distal extremity 24 of the elongate tubular member 22, preferentially begins to move and assume the planar configuration due to the lubricious surface of the hypotube tip 105 and the ease with which the membrane 33 slides thereupon. Expansion proceeds with the middle coil 67 causing the membrane 33 to expand to its desired 5 size. The proximal coil 66 expands last, to centralize and stabilize the configuration so that the push-pull wire 81 is centered with respect to the middle coil 67 and the fully expanded membrane 33.

[0057] Throughout the deployment process, as the coil 34 is expanding and seeking its memorized configuration it is rotating in a leftward or counter-clockwise direction. As a 10 result, the push-pull member 81 is being torqued by the slightly rotating coil 34 in the same direction. This torque requires that the push-pull member 81 be permitted to rotate counter-clockwise in order for the coil 34 to operatively rotate and expand within, and without damaging, the membrane 33 as hereinafter discussed. Furthermore, the amount of torque developed by the expanding coil 34 varies so that more torque is developed and, therefore, 15 more rotation of the push-pull member 81 is optimal, during deployment of the distal portion of the coil 34. In all, the push-pull member 81 rotates approximately 1 to 3, preferably approximately 1.5 to 2, revolutions. As hereinafter discussed, when the operator pushes the freely rotatable handle 131 distally, the variable pitch threaded inner handle 122 effects such a counter-clockwise, controlled, torqued deployment.

[0058] The counter-clockwise rotation during deployment is provided and controlled by 20 rotation means or mechanism which comprises the threaded 125 portion of the inner handle 122 traveling longitudinally and rotationally through the square shaped inner bushing or nut 126 of the outer handle member 123. The lesser or tighter pitch of the thread 125 at the distal segment of the inner handle 122 causes greater rotation during deployment of the distal coil 25 68. It should be appreciated that the direction of rotation of the expansile member depends upon the orientation in which the coil is manufactured. It is, therefore, only important that the rotation means be manufactured to provide controlled rotation in the same direction as that which the coil seeks during expansion according to its manufactured orientation.

[0059] Furthermore, the hypotube casing 132 and the rotatable collar 133 enable the 30 operator to ergonomically and stably maintain a hand hold on the handle 131 of the device 21 during operation thereof without having to remove his or her hand in order to accommodate or permit rotation of the inner handle member 122. This is effected by the free rotation of the

inner handle support tube 127, the push-pull member 81 and the back stop member 134 within the casing 132 and rotatable collar 133. That is, the handle assembly 131 accommodates rotation of the deployment means 80 and expansile member 32 without, or independent of, the portions of the handle assembly 131 held by the operator.

- 5 [0060] During expansion of the expansile member 32 the membrane 33 covering the coil 34 simultaneously constrains the coil 34, thus exerting counteractive or countervailing contractile forces on the expanding coil 34 which is seeking its memorized, ellipsoidal, bi-conical, free or unconstrained configuration. Thus, the membrane 33 does not expand passively. Rather, the expanding coil 34 forcibly expands the membrane 33 to cause the non-planar turns or coils 66, 67 and 68 of the coil 34 to assume a substantially planar or disk-like configuration with the membrane 33 being taut and disposed on opposite sides of the expansile member 32 to form an expansile assembly 31 which when expanded is generally perpendicular to the longitudinal axis of the first flexible elongate tubular member 22. The expansile member 32, when so deployed into this constrained, partially expanded
- 10 configuration, is sufficiently rigid and robust so as to provide a supporting framework for the membrane 33 to keep it taut and capable of occluding an opening. In addition, deployment of the expansile assembly 31 is effected without obstructing or impinging on walls of the smallest openings in the body due to the uniquely small profile and expansion mechanics of the helical coil 34 during deployment and de-deployment as hereinbefore discussed.
- 15 [0061] Another embodiment of the expansile device of the present invention is shown in Figures 6 and 7. Device 221 is similar to device 21 with the principle difference being in the expanded configuration of device 221. Thus all parts of closure device 221 that are identical to those of device 21 carry the same numbers as those of the closure device 21. In addition, device 221 is provided with means for urging the membrane 33 into a partially convex
- 20 configuration during movement of expansile member 32 between contracted and expanded configurations to seal a puncture. Inner handle 122 of device 221 carries a piston 222 which replaces collar 124 in device 21. Piston 222 is made of any suitable material, preferably a compressible or deformable silicone O-ring, and is of an appropriate diameter slightly larger than the inner diameter of outer handle 123. Piston or O-ring 222 is mounted to inner handle
- 25 122 in an appropriate manner similar to that hereinbefore described for collar 124 of device 21. Outer handle 123 is provided with a small transverse hole 223 located at a predetermined, appropriate point along the longitudinal axis of outer handle 123. Hole 223 has an appropriate diameter ranging from approximately 0.005-0.050 inches, preferably
- 30

approximately 0.020 inches. Operation and use of device 221 is the same as that of device 21.

[0062] The primary difference between device 21 and device 221 is the configuration that membrane 33 assumes during deployment, when expansile assembly 31 is in the fully

5 expanded configuration, occluding or sealing a vascular puncture. During deployment of device 221, as inner handle 122 rotates and slides distally within outer handle 123, piston 222 maintains a substantially air-tight seal between inner and outer handles 122 and 123. Thus, as long as piston 222 is disposed proximal of hole 223, air naturally contained between inner and outer handles 122 and 123 and within lumen 26 of elongate tubular member 22 is
10 displaced or vented out of outer handle 123 through hole 223 as inner handle 122 moves distally. When piston 222 becomes disposed distal of hole 223, continued distal movement of inner handle 122 within outer handle 123 forcibly displaces a predetermined volume of air, retained both in between inner and outer handles 122 and 123 and within lumen 26 of elongate tubular member 22, into membrane 33.

15 [0063] As hereinbefore described in conjunction with device 21, during expansion of device 221, the non-adherent portion of membrane 33, distal to the portion of membrane 33 fixed to distal extremity 24 of elongate tubular member 22, begins to move preferentially. With the compression and introduction of the small quantity of air from lumen 26, the deployment of coil 34 into membrane 33 causes the proximal outer surface 224 of membrane
20 33 to assume a substantially different configuration from the distal outer surface 226 of membrane 33 as seen in Figure 1. The taper of proximal outer surface 224 assumes a substantially convex configuration in the expanded configuration instead of the substantially disk-like configuration of the proximal side of membrane 33 in expanded device 21. Similar to membrane 33 of device 21, distal outer surface 226 of membrane 33 of device 221
25 maintains a disk-like configuration when device 221 is in the fully expanded configuration within the vascular puncture.

[0064] Due to the durometer of the membrane material, the alteration in taper of proximal outer surface 224 of membrane 33 of device 221 occurs at pressures very close to the mean arterial pressure of a human patient. Thus, the disk-like configured distal outer surface 226
30 of membrane 33 of expansile assembly 31 is naturally urged or forced laterally by arterial blood flow within the vessel, towards the inner wall of the vessel whereby the tapered

proximal outer surface 224 is caused to more tightly occlude the puncture in the wall of the vessel without the expansile assembly 31 obstructing ongoing blood flow.

[0065] Another embodiment of the expansile device of the present invention is shown in Figure 8. Device 231 is similar to device 221 with the principle difference being in the

5 expanded configuration of device 231. Thus all parts of closure device 231 that are identical to those of device 221 carry the same numbers as those of the closure device 221. In addition, device 231 is provided with means for urging the proximal outer surface 224 of membrane 33 into a convex configuration during movement of expansile assembly 31 between contracted and expanded configurations that is distinct from the urging means of

10 device 221. Expansile member 32 is provided with an additional proximal coil 232.

Additional proximal coil 232 is of substantially equal size and diameter to proximal coil 66. In the free or unconstrained configuration of helical coil 34, proximal coils 66 and 232 lie immediately adjacent to one another like two coils of a tightly wound spring. Thus, the overall unconstrained configuration and size of coil 34 is essentially unchanged from that of

15 device 221.

[0066] Operation of device 231 is substantially the same as that of device 21 with the main difference being in the expanded configuration which device 231 assumes. In addition, second proximal coil 232 requires that, in order to be fully deployed, device 231 be provided with a slightly increased stroke length (not shown). During movement of the expansile

20 member 32 from the contracted to the expanded configuration, due to the additional stiffness and bulk provided by tightly apposed proximal coils 66 and 232, the proximal outer surface 224 of membrane 33 is tented or tapered between the two coils 66 and 232 and assumes a substantially convex configuration as opposed to the substantially disk-like configuration of both sides of membrane 33 assumed by device 21 in the expanded configuration. Double

25 coils 66 and 232 stretch or unwind less when tension is applied to fully deployed device 231. Thus, proximal outer surface 224 of membrane 33 is more firmly supported when device 231 is under tension. In addition, as shown in Figure 8b, depending on the stiffness provided the proximal coils 66 and 232, they can be made to separate slightly under tension so that during deployment of device 231, proximal coil 66 remains inside and up against the inner vessel

30 wall of the puncture while proximal coil 232 is made to pull proximally, through the arteriotomy or puncture in the vessel, and come to rest on the outer wall thereof. In this manner the inner and outer walls of the artery are, essentially, sandwiched or gently compressed between proximal coils 66 and 232 whereupon any additional external proximal

tension may be eliminated or discontinued. This is particularly useful for larger arteriotomies or punctures.

[0067] Referring now to Figs. 9A through 9D, another embodiment of the expandible device 300 for use in a body lumen or tract according to the principles of the present invention is illustrated. The expandible device 300 generally comprises a tubular member 22 having a proximal end 23 and a distal end 24. An expandible member 302 is disposed on the distal end 24 of the tubular member 22. The expandible member 302 has a contracted configuration and an expanded configuration. The expanded configuration comprises a conical spring shape in a free, unconstrained state. A deformable membrane 33 is at least partially disposed over the expandible member 302 in the expanded configuration.

[0068] The expandible member 302 may comprise a coil or spring of wire formed from suitable materials such as shape memory, superelastic material (e.g., NitinolTM), or any material which may be elongated, contracted or constrained without permanent deformation, but when freed or unconstrained (i.e., at body temperature) returns to the normal conical coil configuration. The diameter of the wire may range from about 0.005 inch to about 0.012 inch, preferably from about 0.006 inch to about 0.010 inch. The expandible member 302 may comprise 1 to 10 loops, preferably 3 to 5 loops. The wire is annealed and configured such that the coil 302 in the free state has a height, between the first and the last loop, in a range from about 0.1 inch to about 0.5 inch, preferably from about 0.2 inch to about 0.4 inch.

[0069] As shown in Fig. 9B, the expandible member 302 includes a straight portion 73 extending from an apex of the conical shaped expandible member 302 to the deployment means 80 of the tubular member 22. The deployment means 80 is coupleable to the proximal end 23 of the tubular member 22 as discussed above in detail. The straight section 73 extends from the smallest loop through a center of the coil 302 towards the largest loop and beyond. A free end of the coil may be beaded 304 to protect the membrane 33 when the coil 302 is deployed. The bead 304 may have a diameter that is in a range from about 0.001 inch to about 0.010 inch larger than the coil diameter. The beading 304 of the coil can be accomplished by arch welding, laser, or like means.

[0070] A method for sealing a puncture site is illustrated in Figs. 9B-9D. An expandible device 300 is provided having a tubular member 22, an expandible member 302 disposed on a distal end 24 of the tubular member 22 moveable between a contracted configuration and an expanded configuration, and a deformable membrane 33 at least partially disposed over the

expandible member 302 in the expanded configuration. The device 300 is inserted in the puncture site 306, which may comprise a blood vessel wall as shown or a tissue tract. The expandible member 302 is then deployed to an expanded configuration comprising a conical shape. As shown in Fig. 9B, when the device 300 is deployed, first the largest loop with the
5 beaded tip 304 extends out of the tubular member 22, then the smaller loops, and finally a straight portion 73 of the expandible member 302. The straight portion 73 extends from the apex of the conical shape which is orientated away from the puncture site 306. The membrane 33 provides a continuous barrier over the expandible member 302, particularly on an outer surface in contact with the puncture site 306 to seal the hole and prevent blood from
10 leaking out.

[0071] Referring now to Fig. 9C, when the deployed device 300 is placed against the wall of the vessel 306 and proximal tension is applied to seat the tip assembly, the coils of the expandible member 302 will compress into each other and the cone will transform into a disk shape configuration. As shown in Fig. 9D, further application of proximal tension to the
15 straight section 73 will cause the vessel wall 306 to protrude out so that the expandible member 302 is deformed into an inverted conical shape configuration wherein the apex of the cone is oriented toward the puncture site 306. The expandible device 300 of Figs. 9A-9D provides improved seating of the tip against the puncture site and also enables a user to apply increased tension to the device during the seating process before the device is herniated out of
20 the vessel.

[0072] Referring now to Fig. 10A, an improved membrane attachment 308 according to the principles of the present invention is illustrated. The expandible device 310 for use in a body lumen or tract comprises a tubular member 22, an expandible member 312 disposed on a distal end 24 of the tubular member 22, and a deformable membrane 33 at least partially disposed over the expandible member 312. In particular, a reference stop 314 is disposed between the deformable membrane 33 and the distal end 24 of the tubular member 22 so as to control an angle of deflection of the membrane 33 relative to the tubular member 24.
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[0073] It has been observed and tested that the attachment point 308 of the membrane 33 to the tubular member 22 changes an angle that is formed between the membrane 33 and the
30 tubular member 22 when the device 312 is deployed. In Figs. 10B and 10C, an angle α is formed between the membrane 33 and the tubular member 22. In Figs. 10D and 10E, the membrane attachment 308 is disposed more distally as compared to Figs. 10B and 10C, and

an angle β is formed between the membrane 33 and the tubular member 22. A comparison of these illustrations shows that the closer the attachment point 308 is to the distal end 24 of the tubular member 22 the more perpendicular the deployed membrane 33 becomes to the tubular member 22 at the attachment point 308 as the angle α is greater than the angle β .

- 5 This feature changes the amount of tension that would be required to herniate a deployed device out of the puncture site. In particular, the more perpendicular the deployed membrane is to the tubular member the more is the required pull force to remove the deployed device out of the vessel. This increase in the allowable tension is advantageous as it provides for improved seating of the deployed membrane at the arteriotomy site.
- 10 [0074] Accordingly, a tip stop 314 is employed to provide a reference for consistent attachment 308 of the membrane 33 to the most distal end 24 of the tubular member 22. The reference stop 314 further provides a stop that prevents the membrane 33 and its attachment means 308 to slide forward when the deployed device is under tension. Moreover, the reference stop 314 provides a reservoir of membrane at deployment time proximal to the 15 deploying expandible member 312. As shown in Fig. 10A, the reference stop 314 may comprise a hypotube having length in the range from about 0.010 inch to about 0.200 inch, preferably from about 0.030 inch to about 0.060 inch. The reference stop 314 has an inner diameter that is slightly larger than an outer diameter of the tubular shaft 22. The reference stop 314 has an outer diameter that is in a range from about 0.001 inch to about 0.020 inch,
- 20 preferably from about 0.002 inch to about 0.010 inch larger than the outer diameter of the tubular member 22. The deformable membrane 33 comprises a spherical shape 316 when the expandible member 312 is in the expanded configuration, as seen in Fig. 10E. It will be appreciated however that the deformable membrane 33 may comprise any of the configurations discussed herein, including a conical shape, bi-conical shape, disk shape, 25 convex shape, etc.

- [0075] A proximal end 151 of the membrane 33 is attached to the tubular member 22 just proximal of the reference stop 314 by variety of means. For example, a suture material 318, such as 5-0 braided silk suture, may be used to wrap the membrane end 151 over the tubular member for a length of about 0.050 inch to about 0.50 inch, preferably about 0.10 inch to 30 about 0.20 inch. Alternatively, this may also be accomplished by swaging or crimping a stainless or other metallic tubes of appropriate diameter and length over the membrane end 151. Still further, a preformed coil spring of appropriate wire diameter (e.g., 0.002 inch to about 0.010 inch), with appropriate pitch and coil length may be placed over the membrane

end 151. The membrane end 151 with the attachment means (e.g., suture, swaged metal tube, or coil) are then covered with a cover tube 105. The cover tube 105, as described above, is may be formed from polyimide, peek material, or other medical grade material. The cover tube 105 should be long enough to extend to a proximal end of the reference stop 314, cover 5 the fastened membrane end 151, and extend to or beyond a proximal end of the fastened membrane end 151. The cover tube 105 generally has an inner diameter that is large enough to slide over the fastened membrane end 151 and has a wall thickness of approximately 0.001 inch. A proximal end of the cover tube 105 is glued as indicated by reference numeral 320.

[0076] Referring now to Figs. 11A through 11E, another embodiment of the expandible 10 device 400 for use in a body lumen or tract according to the principles of the present invention is illustrated. The device 400 for use in a body lumen or tract comprises a tubular member 22 having a proximal end 23 and a distal end 24. A first expandible member 312 is disposed on a distal end 24 of the tubular member 22. The first expandible member 312 has a contracted configuration and an expanded configuration comprising a spherical shape. A first 15 deformable membrane 33 is at least partially disposed over the first expandible member 312 in the expanded configuration. A second expandible member 402 is disposed proximal the first expandible member 312 on a distal end 24 of the tubular member 22. The second expandible member 402 has a contracted configuration as shown in Figs. 11A and 11B and expanded configuration comprising a cylindrical shape as shown in Figs. 11C through 11E.

[0077] This design of two expandible members 312 and 402 provided many advantages. 20 For example, the first expandible member 312 at the distal end 24 of the tubular member 22 may locate the vessel wall 306 and anchor the device 400 upon deployment. The first expandible member 312 also provides temporary hemostasis at the puncture site. The second expandible device 402 may be located in the tissue track once the device 400 is located and 25 anchored via the first expandible member 312. The second expandible member 402 provides hemostasis means for the tissue track as well as counteractive force against the first expandible member 312 upon deployment. The second expandible member 402 may also alleviate the need for an external tensioner. These two members 312 and 402, when deployed, work against each other by sandwiching and/or compressing the vessel wall 306 at 30 the puncture site. The device 400 may result in enhanced hemostasis of the arteriotomy site and provide means for hemostasis of the tissue track.

[0078] Referring now to Figs. 11C and 11D, the second expandible member 402 may comprise a variety of embodiments. For example, the second expandible member 402 may comprise a membrane 404 which is inflatable with a predetermined volume of air 406 contained within the tubular member 22. As shown in Fig. 11C, this provides at least one of 5 radial expansion, as depicted by arrows 408, or axial expansion, as depicted by arrows 410, of the second expandible member 402. Alternatively, the second expandible member 402 may comprise a coil or spring of wire 412 and a second deformable membrane 414 at least partially disposed over the coil 412 in the expanded configuration, as shown in Fig. 11D, and similar to the configurations described herein with respect to the first expandible member 10 (32, 302, 312). The coil 412 may have a diameter in a range from about 0.02 inch to about 0.2 inch and may be constructed from wire having a diameter in a range from about 0.005 inch to about 0.02 inch. Additionally, ribs 416 may be formed on an outer surface of the second deformable membrane 414 to secure the tubular member 22 against the tissue track and thereby prevent the device 400 from unintentional sliding or movement. The membranes 404 15 and 414 may be formed from materials as already described with respect to membrane 33. The first expandible member 312 may comprise any of the several embodiments already discussed above in detail.

[0079] Referring now to Fig. 11E, a method for sealing a puncture site is illustrated. An expandible device 400 as described above is provided. The device 400 is inserted in the 20 puncture site. The first expandible member 312 is deployed to an expanded configuration comprising a spherical shape. The second expandible member 402 is deployed to an expanded configuration comprising a cylindrical shape. The first and second expandible members may be deployed sequentially or simultaneously. Preferably, second expandible member 402 is deployed after confirmation that the first expandible member 312 is against 25 the inner wall of the vessel at the puncture site by pulling the tubular member proximally until resistance is felt. The first expandible member 312 is preferably deployed against the blood vessel wall 306. The second expandible member is preferably deployed against a tract 418 of tissue 420. The second expandible member 402 may extend at least a portion of the tissue track 418 or the whole length of the tissue track 418 from the vessel wall 306 to a skin 30 surface 422. Typically, the second expandible member 402 has a length in a range from about 0.1 inch to about 2 inches.

[0080] After an adequate amount of time, the device 400 is un-deployed. The un-deployment may include the un-deployment of both expandible members 312 and 402 and

removal of the device 400 or it may require a two stage sequential un-deployment. The two stage un-deployment may preferably comprise un-deployment of the first expansile member 312 initially followed by un-deployment of the second expansile member 402 and removal of the device 402 some time later.

5 [0081] It is apparent from the foregoing that there has been provided an expansile device for use in blood vessels and tracts in the human body and more particularly for percutaneous occlusion of vascular access sites in the human body and method of using and manufacturing the same.

10 [0082] Although the expansile device and method have been described principally in use with the human body it should be appreciated that the expansile device and method also can be utilized with animals in a similar manner.

[0083] In addition, it should be appreciated that the expansile device can be used within many different natural and iatrogenically created tracts in the body in order to provide for other therapeutic or prophylactic modalities.

15 [0084] Thus, it is also apparent from the foregoing that there has been provided a expansile device and method for percutaneous access and occlusion of openings and tracts in the human body that have distinct advantages over those heretofore provided.